

WOLBACHIA AND OXITEC MOSQUITO REGISTRATIONS

ISSUE/TOPIC: Biotechnology, Pesticides, Wolbachia, Bacteria and Genetically Engineered Mosquitos

BACKGROUND:

- The EPA registers biopesticides, which include alterations of mosquito species to reduce mosquito populations. Two technologies pending or anticipated at the EPA involve release of sterilized male mosquitos. When the altered mosquitos are released and mate with wild female mosquitos, the offspring are not viable.
- One technique introduces Wolbachia bacteria, found naturally in many insect species, into male mosquitos. The EPA is reviewing MosquitoMate's Wolbachia ZAP *Aedes albopictus* pesticide registration application and intends to make a decision in June. Anticipated use sites exclude Florida and southern states because the EPA has determined additional efficacy data are needed for those geographic regions.
- The EPA is also reviewing an experimental use permit (EUP) amendment/extension for Wolbachia WB1 strain in *Aedes aegypti* mosquitoes to add new sites in Texas and Florida where Zika could be present, as well as a new manufacturing process for producing male mosquitoes for release. The EPA anticipates being able to make a decision in September 2017.
- Another technique involves genetically engineered *Aedes aegypti* mosquitoes. This so-called "Oxitec" mosquito is currently regulated by the FDA as a new animal drug under the Federal Food, Drug, and Cosmetic Act and has yet to be approved for general use. FDA has proposed to transfer jurisdiction to the EPA through a published draft guidance document.
- While awaiting the anticipated jurisdiction change, the EPA can accept an Oxitec application for a pesticide experimental use permit and for an emergency exemption (Section 18).
- Sen. Inhofe inquiry supporting approval of "Oxitec" mosquito.

TALKING POINTS:

- The EPA is actively working on Wolbachia actions and is involved with the registrant and FDA on Oxitec Male Mosquito actions.
- Oxitec's genetically engineered mosquitos and MosquitoMate's Wolbachia mosquitoes are emerging biotechnology pesticides that could be used to combat the spread of vector-borne diseases, such as Zika.